The European Agency for the Evaluation of Medicinal Products
Human Medicines Evaluation Unit

25 February 1999
CPMP/573/1999

PUBLIC STATEMENT ON
TROVAN IV & TURVEL IV

In consultation with the EMEA the Marketing Authorisation Holders for Trovan IV (Pfizer Research Limited) and Turvel IV (Roerig Farmaceutici Italiana S.p.A..) have recently submitted variation applications to introduce changes to the Summary of Product Characteristics (SPC) and Package Leaflets of these products. The variation to the labelling adds, to the already existing information on incompatibility with 0.9% Sodium Chloride Injection (normal saline), information on the potential incompatibility of alatrofloxacin mesylate concentrate for solution for infusion with Lactated Ringer's Injection.

The need to introduce these changes was identified as a precautionary measure following completion and review of a series of *in vitro* compatibility studies with alatrofloxacin and normal saline and Lactated Ringer's Injection.

Specific changes have been introduced to Section 4.2 – *Posology and method of administration*, 6.2 - *Incompatibilities* and 6.6 -*Instructions for use and handling and disposal* of the SPC together with changes to the section on *Compatibility and Stability* in the Package Leaflet. The changes, which are repeated in the sections mentioned above, are as follows in italicised text:

"Trovan IV/ Turvel IV should not be diluted with 0.9% Sodium Chloride Injection, (normal saline), *alone or in combination with other diluents. A precipitate may form under these conditions. In addition, Trovan IV/ Turvel IV should not be diluted with Lactated Ringer's*

Normal saline, 0.9% Sodium Chloride Injection can be used for flushing I.V. lines prior to or after administration of Trovan IV/ Turvel IV."

Health Care Professionals should carefully follow the instructions included in the current labelling for Trovan IV and Turvel IV when preparing alatrofloxacin mesylate concentrate for solution for infusion for administration. In particular it should be noted that Trovan IV or Turvel IV can be diluted only with the following diluents:

5% Dextrose Injection
0.45% Sodium Chloride Injection
5% Dextrose and 0.45% Sodium Chloride Injection
5% Dextrose and 0.2% Sodium Chloride Injection
Lactated Ringer's and 5% Dextrose Injection

The scientific committee of the EMEA, the CPMP, adopted positive opinions on the introduction of the above amendments to the SPC and Package Leaflet for Trovan IV and Turvel IV during the course of its February meeting (23-25th February). These opinions will now be forwarded to the Commission to initiate the Decision-Making Process. In the interim the draft SPC and Package leaflet including these revisions may be found in the European Public Assessment Reports (EPARs) for these products (http://www.eudra.org/emea.html). The Marketing Authorisation Holders have also undertaken to write to concerned healthcare professionals in EU markets, to inform them of the introduction of this new information and to reinforce the instructions for correct use and administration of Trovan IV / Turvel IV.

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